

Summary of Product Characteristics (SmPC)

1. Name of Medicinal Product

MIXANAL Caplet

2. Qualitative and quantitative composition

Active Ingredients

Composition :

Each caplet contains:

Paracetamol 500 mg

Caffeine anhydrous (Guaranine) 30 mg

3. Pharmaceutical Form

Caplet

Description : White with red spot and specific odour, caplet no. 2, with "D/K" emboss on one side and "MXL" emboss on the other side with unidirectional position.

4. Clinical Particulars

4.1 Therapeutic Indications

To reduce and relieve the symptoms of headache, dizziness, fever, toothache, pain during menstruation, muscle pain and joint ache.

Information of medicine :

- **Mixanal is indicated for headache and toothache**

- Mixanal relieves headache and dizziness

- Mixanal is also effective to reduce fever and relieve other pains such as :

Toothache, pain during menstruation, muscle pain, and joint ache.

- Mixanal act fast and the effect appears in a few minutes

- Mixanal has a long duration of action

- Mixanal is safe because it does not contain metamizol, acetyl salicylic acid or salicylamide

- Mixanal does not cause pain in the stomach, does not have the potency to cause impairment on red blood cells, and does not cause sleepiness

Pharmacology Act as analgesic for acute painful and antipyretic. Caffeine enhances the analgesic efficacy of acetaminophen.

For oral administration.

4.2 Posology and method of administration

- Adults : 1-2 caplets, 3-4 times daily

4.3 Contraindications

- Hepatic dysfunction
- Not to be used in patients who are allergic to this product

4.4 Special warnings and precautions for use

- Use with caution in patients with renal insufficiency and hepatic failure
- Avoid in ulcer patients, asthmatics, diabetics, and during pregnancy

4.5 Pregnancy and Lactation

Pregnancy

Paracetamol

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency

Lactation

Paracetamol is excreted in breast milk but not in a clinically significant amount.

Not to be used during lactation unless considered essential by a physician.

4.6 Effects on ability to drive and use machines

No adverse effects known.

4.7 Side effect

- Paracetamol may cause hepatotoxic effect.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important.

It allows continued monitoring of the benefit/ risk balance of the medicinal product.

4.8 Overdose

Paracetamol

Liver damage is possible in adults who have taken 10g or more of paracetamol.

Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk Factors

If the patient

a) Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes or

b) Regularly consumes ethanol in excess of recommended amounts or

c) Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia

Symptoms of paracetamol overdose in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral odema and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Management

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of the overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section. Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable) but results should not delay initiation of treatment beyond 8 hours after ingestion, as the effectiveness of the antidote declines sharply after this

time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside of hospital.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Paracetamol is a peripherally acting analgesic with antipyretic activity.

Caffeine acts on the central nervous system producing a condition of wakefulness and increased mental activity.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and completely absorbed with peak plasma levels seen within 30 to 60 minutes. Less than 50% is protein bound and the drug is uniformly distributed throughout the body fluids. Paracetamol is eliminated by metabolism to inactive conjugates followed by urinary excretion. The half life is 2.75 - 3.25 hours.

Paracetamol is metabolised predominantly in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates.

Caffeine is readily absorbed after oral administration and is widely distributed throughout the body. Caffeine passes readily into the central nervous system and into saliva. In adults caffeine is metabolised almost completely via oxidation, demethylation and acetylation with only about 1% excreted unchanged. Elimination half life is about 3-6 hours in adults.

5.3 Preclinical safety data

None stated.

6. Pharmaceutical Particulars

6.1 List of excipients

- Hydroxypropyl Cellulose
- Sodium Starch Glycolate
- FD&C Ponceau 4R Dye
- Colloidal silicon dioxide
- Corn starch
- Magnesium stearate

- Powder strawberry
- PEG 6000 powder
- Talc
- Microcrystalline cellulose

6.2 Incompatibilities

None.

6.3 Shelf life

60 months

6.4 Special precautions for storage

Protect from light. **Store below 30°C.**

Keep all medicines out of reach of children

6.5 Nature and contents of container

Primary packaging : Polycellonium foil strip

Secondary packaging : Catch cover: Artpaper 85 g/m². Box: Duplex coated 270 g/m² + Water Based.

Packing : Box, 25 Catch cover @ 1 strip @ 4 caplets (envelope containing 4 caplets in aluminium strip).

6.6 Special precautions for disposal and other handling

None.

7. Marketing Authorization Holder and Manufacturer

Applicant (MAH) :

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